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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,355	12/29/2000	William F. Polley	56301P551	9724

8791 7590 04/24/2003

BLAKELY SOKOLOFF TAYLOR & ZAFMAN  
12400 WILSHIRE BOULEVARD, SEVENTH FLOOR  
LOS ANGELES, CA 90025

EXAMINER
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FLYNN, AMANDA R

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 04/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/753,355	POLLEY ET AL.
	Examiner	Art Unit
	Amanda R. Flynn	3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 03 February 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 16-30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 16-30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 15 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The 35 U.S. C. 112, second paragraph rejections cited in the prior office action have been overcome by the amendment filed on 3 February 2003. Therefore, the rejections are withdrawn.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,188,605 to Sleep.

Sleep discloses an introducer comprising a circular finger tab portion 54, a tube portion 40 and a hinge portion 60, placed between the finger tab and tube portions, forming a “seamless” introducer. Sleep states that the tube portion is substantially hollow, having a diameter sufficient to accommodate a balloon catheter (col. 3, lines 47-51). Further, Sleep discloses a scoreline, or a “line of weakness” 52, along the tube portion of the introducer.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sleep in view of U.S. Patent Number 5,263,938 to Orr et al.

Sleep discloses the previously described introducer, but does not disclose that the introducer is made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its "semi-rigid" properties (col. 3, lines 34-37).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Sleep, with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

6. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sleep.

Sleep discloses the previously described "seamless" introducer, wherein the enlarged tube portion 44 and finger tab portion 54 are integrally molded, and integrally attached to tube portion 44. While Sleep discloses that the enlarged tube portion, the finger tab portion and the tube portion are integrally connected, Sleep does not disclose that they are formed as a single integral piece.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the introducer as disclosed by Sleep with an integral tube and finger tab portion, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

*Howard v. Detroit Stove Works*, 150 U.S.

7. Claims 25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,1671634 to Corrigan, Jr. et al.

Corrigan, Jr. et al. disclose an introducer comprising a substantially hollow tube 18, first and second rectangular finger tab portions 14 that are formed at the proximal end of the tube "without seams," and a scoreline 26 formed along the tube. Corrigan, Jr. et al. disclose that the scoreline extends to a beveled and tapered portion 25 at the distal tip of the introducer. While Corrigan Jr. et al. disclose that the tube and finger tab portions are fit together into a "seamless" introducer, Corrigan Jr. et al. do not disclose that the finger tab portions are formed as a single integral piece with the tube.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the introducer as disclosed by Corrigan Jr. et al. with an integral tube and dual finger tab portions, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S.

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,1671634 to Corrigan, Jr. et al. in view of U.S. Patent Number 5,782,817 to Franzel et al.

Corrigan, Jr. et al. disclose the previously described introducer, but do not disclose a safety valve coupled to the proximal end of the introducer.

Franzel et al. disclose an introducer with a toroidal safety valve 18 on the proximal end of the introducer, to prevent backflow of blood (col. 2, lines 58-60).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Corrigan, Jr. et al., with a safety valve as taught by Franzel et al., to prevent backflow of blood during use.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrigan, Jr. et al., in view of Orr et al.

Corrigan, Jr. et al. disclose the previously described introducer, but do not disclose that the introducer is made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its “semi-rigid” properties (col. 3, lines 34-37).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Corrigan, Jr. et al., with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

***Response to Arguments***

10. Applicant’s arguments entered on 3 February 2003 have been carefully reviewed by the examiner, but are not deemed persuasive.

Beginning on page 5 of the response, Applicant asserts that the hinge (60), identified in the Sleep patent is a “v-shaped notch” and not a “hinge”. According to Merriam-Webster’s Collegiate Dictionary (10<sup>th</sup> edition), a hinge is “a flexible ligamentous joint”. As described in the Sleep reference, the hinge (60) narrows to a line of weakness (52), such that the introducer can be pulled away from an inserted catheter, beginning at the hinged joint (60). The hinge disclosed by Sleep functions in an identical manner as the hinge disclosed in the present application, insofar as the instant hinge has been structurally defined.

In regard to claims 21-24, Applicant argues that Sleep does not teach a tube and tabbed portion that are formed as a single integral piece. This limitation has been newly added to the

claim, via amendment, and has been handled above in paragraph 6. This new ground of rejection was necessitated by Applicant's amendment filed on 3 February 2003.

Also regarding claims 21-24, Applicant asserts that the Sleep reference does not teach a scoreline along the tube portion of the introducer. As seen in Figure 2, a scoreline, or "line of weakness" (52) runs along the length of the introducer, including the enlarged tube portion (44) and the tube portion (40). Applicant also asserts that the Sleep reference does not teach a scoreline comprising a "set of slits which define a scoreline." Firstly, neither Applicant's disclosure nor claims nor drawings identify the scoreline as a "set of slits," as argued. The drawings (see Figure 7) depict the scoreline as a unitary marking, while the specification simply states that the scoreline "is used to make it easier to pull away finger tab 244 from catheter 249" (page 10). Neither the drawings nor the specification define any structure, including the stated "set of slits". Secondly, while the Sleep reference states that the line of weakness is preferable <sup>to</sup> a slit running through the wall of the tube, it is depicted (see Figure 2) as a "set of slits" indicated by the hash marks shown.

On page 7, regarding claims 25-30, Applicant argues that Corrigan, Jr. et al. do not teach a tube that is formed as a single integral piece with first and second finger tab portions. This limitation has been newly added to the claim, via amendment, and has been handled above in paragraph 7. This new ground of rejection was necessitated by Applicant's amendment filed on 3 February 2003.

Further, Applicant argues that Corrigan, Jr. et al. teach away from forming the finger tabs and tube as a single integral piece. The Examiner disagrees with this interpretation of the reference. Corrigan, Jr. et al. disclose that the finger tabs (14) are bonded to respective portions

(28) of the peelable sheath (12). As stated in column 3, line 61-63, the sheath (12) comprises a hollow, flexible tube (18). Therefore, when Corrigan, Jr. et al. state that "wings 14 are bonded to sheath 12," the wings are in fact also bonded to the hollow tube (18). Given the knowledge that the tube (18) and finger tab portions (14) are bonded together, no part of the Corrigan, Jr. et al. reference teaches away from forming the tube and tab portions as a single integral piece. It would have been obvious to have provided the introducer as disclosed by Corrigan Jr. et al. with an integral tube and finger tab portion, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

### *Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on 703-308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

*Amanda R. Flynn*  
Amanda R. Flynn  
Examiner  
Art Unit 3751

*arf*  
arf  
April 15, 2003

*[Signature]* 4-18-03  
GREGORY HUSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700